

REMARKS

Claims 1-25 are pending. Claims 1-3, 12-14, and 16 are amended to address informalities noted in the Office Action. No new matter has been introduced.

Restriction

Applicants note that dependent method and process claims should be rejoined by the PTO upon a determination that the elected product is allowable, pursuant to the PTO's *Ochiai/Brouwer* guidelines.

Abstract

A new abstract is submitted herewith, which fully complies with Rule 72(b)'s word limit of 150.

Double Patenting

In view of the possibility that claim 1 may be further amended or separated in a divisional application, applicants will defer responding to the rejection.

35 USC 112, First Paragraph

Claim 16 has been rejected under the first paragraph of 35 U.S.C. 112 on the basis that the recited peptide is not known to the Examiner as being an LH-RH antagonist. Applicants note that the specification confirms it is an active LH-RH antagonist. In the absence of specific reason to doubt the activity of this particular species, the rejection should be withdrawn. The rejection has offered no evidence of unpredictability among the recited species of antagonists. The rejection cites the *Wands* factors, but there is no application of the *Wands* factors to the facts of this application, nor is any reference cited showing a reason to doubt the activity of this specific compound among the group of preferred compounds identified in the specification. The mere recitation of the *Wands* factors, in the absence of other evidence, cannot overcome the specification's presumption of enablement. Accordingly, withdrawal of the rejection is respectfully requested.

35 USC 112, Second Paragraph

Claims 1-3 and 11-16 have been rejected under the second paragraph of 35 USC 112 for indefiniteness. In response, claims 1-3 have been amended to remove the superfluous word "may". As for the word "about", applicants maintain that this is accepted claim terminology in chemical practice dating back several decades. Claim 16 has been clarified to recite "acetate salt". Accordingly, withdrawal of the rejection is requested.

35 USC 102(e)

Claims 1-3 and 11 have been rejected under 35 USC 102(e) as anticipated by Haviv '904. Claims 1-3 and 11-15 have been rejected under 35 USC 103 as obvious over Haviv '904 in view of Boswell. Claim 1 has been rejected under 35 USC 103 as obvious over Haviv '009 in view of Boswell.

Concerning the alleged anticipation of claims 1-3 and 11 by Haviv '904, applicants note that the reference provides a broad range of peptides and a broad range of possible drug delivery compositions. Out of these broad ranges, the rejection zooms in on two types in order to select variables so as to arrive at the present claims. Furthermore, the working examples of this patent do not teach in the direction that the rejection follows, nor are there other apparent blazemarks that point to the selection used in the rejection. Lastly, the action does not point to any teaching in Haviv '904 of a polymer with a terminal carboxyl group as required by the present claims. Under these circumstances, an anticipation rejection cannot stand. When the universe of possible combinations is very large, as it is in the case of Haviv '904, there cannot be anticipation. *In re Sivaramakrishnan*, 213 USPQ 441 (CCPA 1982).

With respect to the obviousness rejections, applicants point out that neither Haviv '904 nor Haviv '009 suggest the desirability of selecting a certain polymer for use with the peptides of the presently claimed invention in a sustained release formulation. As shown by the comparative results in the present specification (see in particular page 58, last paragraph), not just any PLA/PGA copolymer has a terminal carboxyl group. Furthermore, these comparative examples establish the importance of the terminal carboxyl group for successful dissolving of the peptide. The advantage of the presently claimed invention is neither taught nor suggested by the Haviv references, whether they are taken alone or in combination with Boswell.

Accordingly, withdrawal of the prior art rejections is requested.

IDS

Applicants note that the absence of a translation does not relieve the PTO from considering the reference in question when an abstract has been provided.

Conclusion

For the foregoing reasons, applicants respectfully request allowance of the present application.

Respectfully submitted,

Date April 14, 2005

By 

FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.